Prospective, randomized study of cutting balloon angioplasty versus conventional balloon angioplasty for the treatment of hemodialysis access stenoses

Hossam M. Saleh, MD, MRCS,[a] **Ahmed K. Gabr, MD, MRCS,**[a] **Mohamed M. Tawfik, MD,**[a] and **Hesham Abouellail, MD,**[b] *Cairo, Egypt*

Objective: **The aim of this trial was to compare the rates of patency achieved by cutting and conventional balloon angioplasty to treat hemodialysis access stenoses.**

Methods: **End-stage renal failure patients (at three tertiary referral centers) with significant hemodialysis access stenoses were prospectively randomized to have percutaneous transluminal angioplasty (PTA) by either cutting or conventional balloons. Patients with more than one hemodynamically significant stenosis were excluded. Kaplan-Meier method was used to compare the primary assisted patency rates for the two groups.**

Results: **The study randomized 623 patients into two groups, and the duration of follow-up was 15 ± 3 months. In the cutting balloon angioplasty group, the clinical success rate was 89% (282 of 316 stenoses). In the conventional balloon angioplasty group, the clinical success rate was 86% (265 of 307 stenoses; $P = .637$). Assisted primary patency for cutting PTA was statistically significantly higher at 6 months and 1 year (86% and 63%) than that for conventional PTA (56% and 37%, respectively; $P = .037$) in the treatment of stenosis of the graft-to-vein anastomosis. In the venous stenosis subgroup, equivalent primary assisted patency at 6 months and 1 year was observed for cutting PTA (84% and 55%) and conventional PTA (70% and 46%, respectively; $P = .360$). In the intragraft stenosis subgroup, primary assisted patency was equivalent at 6 months and 1 year for cutting PTA (67% and 39%) and conventional PTA (62% and 49%, respectively; $P = .371$). In the arterial anastomotic stenosis subgroup, assisted primary patency at 6 months and 1 year was equivalent for cutting PTA (70% and 30%) and conventional PTA (75% and 33%, respectively; $P = .921$).**

Conclusions: **Cutting balloon angioplasty proved to be a safe and effective treatment of graft-to-vein anastomotic stenosis, with significantly higher patency than that of conventional balloon angioplasty. (J Vasc Surg 2014;60:735-40.)**

Maintenance of long-term patency of hemodialysis vascular access is essential for regular hemodialysis in end-stage renal failure patients. Hemodialysis access failure may occur by thrombosis secondary to stenosis of the anastomosis or the draining vein. Such patients usually need multiple interventions to restore functionality; otherwise, they would require creation of another hemodialysis access. The use of percutaneous transluminal angioplasty (PTA) to treat significant stenosis of hemodialysis access is recommended to prolong the patency of both autogenous arteriovenous fistulas and prosthetic arteriovenous grafts.[1-5] Repeated angioplasty procedures may be necessary to maintain secondary patency of failing hemodialysis access.[2] It is assumed that techniques that improve the patency of arteriovenous fistulas and grafts will limit the number of further procedures necessary to maintain access function. The aim of this trial was to compare the patency achieved by cutting and conventional balloon angioplasty to treat hemodialysis access stenoses.

METHODS

The study was performed at three tertiary referral centers in the Middle East (Prince Salman Hospital, Tabuk; Saudi German Hospital, Riyadh; and Al-Hassa Hospital). Our institutional review board approved the study protocol, and written informed consent was obtained from all patients.

Study design. Patients with different types of hemodialysis access stenoses in whom PTA was indicated were prospectively randomized (by a sealed envelope randomization service[6]) into two groups, one group treated with cutting balloon angioplasty and the other group treated with conventional balloon angioplasty. Table I outlines the demographics of the study population. The treating vascular surgeon evaluated the indication for angioplasty, performed the angioplasty, and monitored the clinical course after angioplasty. Procedural details recorded included access type, location, details of the angioplasty procedure, procedure outcome, and complications. Patients were monitored for angioplasty-related complications, including balloon rupture, vessel injury, aneurysm formation, bleeding, reaction to contrast material,

From the Department of Vascular Surgery[a] and Department of Nephrology,[b] Ain Shams University.

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Reprint requests: Hossam M. Saleh, MD, MRCS, Assistant Professor of Vascular Surgery, Vascular Surgery Department, Ain Shams University Hospitals, El Demerdash Hospital, Ramses St, Abbasia, Cairo, Egypt (e-mail: hosamsaleh2003@yahoo.com).

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Table I. Demographic characteristics of the study population

Characteristic	*Cutting balloon, %*	*Conventional, %*
Age, years		
Mean ± SD	60.4 ± 10	61.9 ± 10
Range	43-79	41-75
Female sex	41	55
Diabetes mellitus	56	49
Hypertension	85	82
Coronary artery disease	24	26
Congestive heart failure	7	9

SD, Standard deviation.

Table II. Exclusion criteria

Previous PTA for the same lesion
PTA combined with stenting
Associated significant (>50%) central venous stenosis
Multiple significant (>50%) stenoses
Previous access thrombectomy
Positive pregnancy test result within 7 days before enrollment
Patient is scheduled for a kidney transplant
Life expectancy <6 months
Allergy to heparin or radiographic contrast material

PTA, Percutaneous transluminal angioplasty.

pulmonary embolism, hypoxia, infection, hand ischemia, and death.

Inclusion criteria. PTAs were performed in end-stage renal failure patients with hemodynamically significant (defined as >50%) stenosis of the autogenous fistula or prosthetic graft.

Exclusion criteria. Exclusion criteria are listed in Table II.

Assessment of stenoses. Screening was done by ultrasonography, with angiography reserved for patients with hemodynamically significant stenoses, to assess the degree and location of stenosis as well as to delineate the outflow veins. All lesions were characterized by location, length, and degree of stenosis. The angiographic criteria were assessed and satisfied before any treatment was performed. The target lesion was imaged in two orthogonal planes. The imaging plane that demonstrated the greatest percentage of stenosis was used for anatomic measurements. The diameter of the adjacent segment of normal vein was used as the reference diameter. The percentage of stenosis was defined as the maximum diameter reduction compared with the reference vessel diameter (Table III).

Procedures and criteria for success. The vascular surgeon performed all procedures with local anesthesia (lidocaine 2%). Heparin (2000 IU) was administered intravenously at the beginning of each procedure. Balloon size was determined according to the measured diameter of the reference vessel or the prosthetic graft. An introducer sheath (5F-7F) was used as an access for angioplasty in all patients.

Technique of PTA. The technique of cutting PTA and the technique of conventional PTA are detailed in the Appendix.

Total procedure time. The total procedure time was documented for each patient. The start of the procedure was defined as the moment when the physician gained percutaneous access into the hemodialysis access. The end of the procedure was determined by the time of completion of final postprocedural fistulography.

Definitions. Clinical success was defined as resumption of at least one session of normal dialysis after angioplasty. Hemodynamic success was defined as restoration of normal blood flow through the treated vascular lesion. Anatomic success was defined as residual stenosis <30% after angioplasty. Successful endovascular intervention was based on these clinical, hemodynamic, and anatomic end points. Assisted primary patency was defined as maintained patency of the treated lesion after angioplasty. Hemodialysis access failure due to restenosis of the treated lesion was considered the end point of assisted primary patency.

Follow-up. Follow-up included clinical examination, dialysis access venous pressure measurement during dialysis, and measurements of dialysis access recirculation, performed every 4 weeks. Measurement of the hemodialysis access flow with ultrasonography was done every 12 weeks. Fistulography was performed when a stenosis of >50% was detected by ultrasonography.

Statistical analysis. The degree of stenosis before angioplasty, residual stenosis after angioplasty, diameter improvement after angioplasty, and diameter of the balloon used in the cutting and conventional balloon angioplasty groups were compared by Mann-Whitney U test. The four types of hemodialysis access stenoses evaluated in our study were located in the venous outflow, at the graft-to-vein anastomosis, within the graft, and at the arterial anastomosis. Venous stenosis was defined as stenosis of the fistula vein from the arteriovenous anastomosis to the central veins (but not including central vein stenosis). The assisted primary patency for these four types of stenoses was assessed by Kaplan-Meier analysis. The log-rank test was used to compare the cutting and conventional PTA groups to determine statistical significance. P values $< .05$ were considered statistically significant. Statistical analysis was performed with Stat-View version 5.0 software (SAS Institute Inc, Cary, NC).

RESULTS

The study prospectively randomized 623 patients with the four described types of hemodialysis access stenoses in whom PTA was indicated into two groups to receive cutting balloon angioplasty or conventional balloon angioplasty. The mean duration of follow-up was 15 ± 3 months.

Cutting balloon angioplasty group. From January 2012 to December 2013, 316 patients (185 men, 131 women) with 316 stenoses underwent cutting PTA. The 316 stenoses consisted of 95 venous, 80 graft-to-vein anastomosis, 61 intragraft, and 80 arterial anastomotic stenoses; 282 patients (89%) achieved clinical success with

Table III. Percentage diameter stenosis before percutaneous transluminal angioplasty (*PTA*), residual percentage diameter stenosis after PTA, and percentage diameter improvement after PTA

	Percentage diameter stenosis before PTA			*Residual percentage diameter stenosis after PTA*			*Percentage diameter improvement after PTA*		
Stenosis type	*Cutting PTA*	*Conventional PTA*	P *value*[a]	*Cutting PTA*	*Conventional PTA*	P *value*[a]	*Cutting PTA*	*Conventional PTA*	P *value*[a]
Venous	80.9 ± 12	74.1 ± 14	.041	30.8 ± 15	26.8 ± 13	.328	50.1 ± 12	47.3 ± 11	.312
Graft-to-vein anastomotic	82.1 ± 16	67.9 ± 13	.060	34.9 ± 12	32.0 ± 12	.372	47.2 ± 13	35.9 ± 12	.041
Intragraft	68.1 ± 18	63.0 ± 9.5	.858	38.9 ± 16	27.9 ± 8.7	.028	29.2 ± 14	35.1 ± 11	.287
Arterial anastomotic	74.8 ± 5.5	72.1 ± 6.1	.327	34.9 ± 11	24.1 ± 15	.096	39.9 ± 16	48 ± 10	.141

[a]*P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the Mann-Whitney *U* test.

Table IV. Diameter and loaded maximum pressure of balloons

	Inflation diameter of balloon, mm			*Loaded maximum pressure, atm*		
Stenosis type	*Cutting PTA*	*Conventional PTA*	P *value*[a]	*Cutting PTA*	*Conventional PTA*	P *value*[a]
Venous	5.6 ± 0.6	5.4 ± 0.5	.862	6.0 ± 4.0	15.1 ± 2.2	.041
Graft-to-vein anastomotic	5.2 ± 0.2	5.1 ± 0.4	.480	6.1 ± 2.2	15.5 ± 3.2	.043
Intragraft	5.4 ± 0.3	5.5 ± 0.6	.487	8.2 ± 2.0	16.7 ± 2.6	0.48
Arterial anastomotic	2.5 ± 0.4	2.8 ± 0.3	.775	8.4 ± 2.6	15.0 ± 2.0	.049

[a]*P* values were derived from comparisons between cutting and conventional PTA groups and were calculated with the Mann-Whitney *U* test.

cutting PTA. Cutting balloon angioplasty failed to achieve clinical success in 34 patients; these patients required stent implantation (12 patients) or surgical intervention (22 patients).

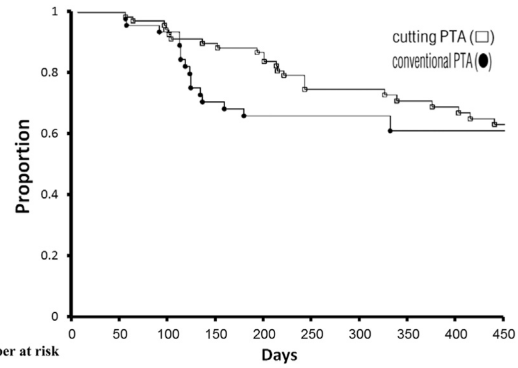
Conventional balloon angioplasty group. From January 2012 to December 2013, 307 patients (137 men, 170 women) with 307 stenoses underwent conventional PTA. The 307 stenoses consisted of 81 venous, 82 graft-to-vein anastomosis, 72 intragraft, and 72 arterial anastomotic stenoses; 265 patients (86%) achieved clinical success with conventional PTA. Conventional balloon angioplasty failed to achieve clinical success in 42 patients; these patients required stent implantation (15 patients), surgical reconstruction (17 patients), or graft insertion (10 patients).

Cutting and conventional balloon angioplasty groups. The mean time of the angioplasty procedure for cutting and conventional balloon angioplasty was 61.2 minutes and 49.6 minutes, respectively ($P = .642$). Differences in the degree of stenosis before angioplasty and the diameter of the balloon used between cutting and conventional balloon angioplasty were not statistically significant for all subgroups (Tables III and IV). Statistically insignificant differences between cutting and conventional balloon angioplasty were seen with regard to residual stenosis after angioplasty in the subgroups for venous stenosis ($P = .328$), stenosis of the graft-to-vein anastomosis ($P = .371$), and arterial anastomotic stenosis ($P = .096$). Differences in the clinical success rates were statistically insignificant between cutting balloon angioplasty (89%) and conventional balloon angioplasty (86%) groups ($P = .637$). Differences in the percentage diameter improvement after angioplasty were statistically significant in favor of the cutting balloon for the subgroup with stenosis of the graft-to-vein anastomosis ($P = .041$). Differences in percentage diameter improvement between the cutting and conventional balloon angioplasty groups were not statistically significant after angioplasty in the subgroups with venous stenosis ($P = .312$), intragraft stenosis ($P = .287$), and arterial anastomotic stenosis ($P = .141$). The degree of stenosis before angioplasty, residual stenosis after angioplasty, and diameter improvement after angioplasty are illustrated in Table III. The balloon diameter and the inflation pressure used are provided in Table IV.

For the venous stenosis subgroup, by Kaplan-Meier analysis, the assisted primary patency at 6 months and 1 year for the cutting balloon angioplasty group was 84% and 55%, respectively, compared with 70% and 46%, respectively, for conventional balloon angioplasty. These differences did not reach statistical significance ($P = .360$) (Fig 1).

However, for the graft-to-vein anastomotic subgroup, the assisted primary patency for the cutting balloon angioplasty group (86% and 63% at 6 months and 1 year, respectively) was significantly better than that for the conventional balloon angioplasty group (56% and 37%; $P = .037$) (Fig 2).

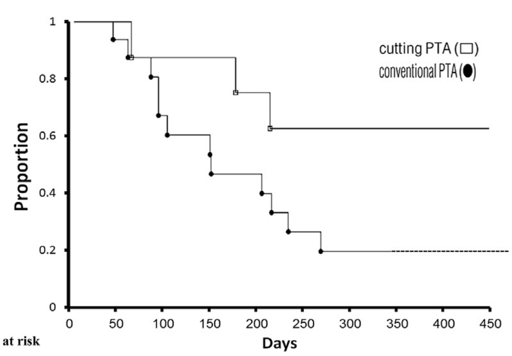
For the intragraft stenosis subgroup, the assisted primary patency for the cutting balloon angioplasty group (67% and 39% at 6 months and 1 year, respectively) and the conventional balloon angioplasty group (75% and 33%) was not statistically significantly different ($P = .371$) (Fig 3).



Number at risk

Cutting	95	85	83	81	79	70	61	52	47	40
Conventional	81	68	65	60	56	50	42	37	30	22

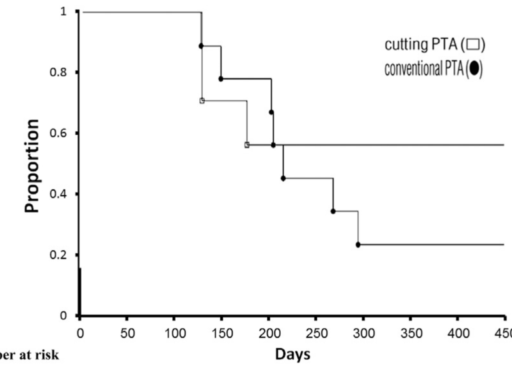
Fig 1. Graph shows the Kaplan-Meier survival analysis for assisted primary patency rates in patients with venous stenosis in the cutting and conventional percutaneous transluminal angioplasty (*PTA*) groups. No significant differences in assisted primary patency rates were identified between groups ($P = .360$). The number of patients at risk in each time period is listed.



Number at risk

Cutting	80	71	70	69	68	62	55	50	43	30
Conventional	82	70	64	55	45	40	35	30	22	11

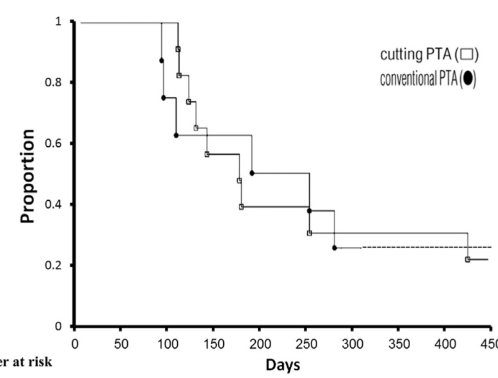
Fig 2. Graph shows the Kaplan-Meier survival analysis for assisted primary patency rates in patients with graft-to-vein anastomotic stenosis in the cutting and conventional percutaneous transluminal angioplasty (*PTA*) groups. The assisted primary patency rate was significantly higher in the cutting PTA group than in the conventional PTA group ($P = .037$). Note that the line is interrupted beyond the point at which standard error exceeds 10%. The number of patients at risk in each time period is listed.



Number at risk

Cutting	61	55	52	48	40	36	30	23	20	15
Conventional	72	63	62	59	54	45	30	23	19	14

Fig 3. Graph shows the Kaplan-Meier survival analysis for assisted primary patency rates in patients with intragraft stenosis in the cutting and conventional percutaneous transluminal angioplasty (*PTA*) groups. No significant differences in assisted primary patency rates were identified between groups ($P = .371$). The number of patients at risk in each time period is listed.



Number at risk

Cutting	80	71	68	60	56	45	30	24	20	18
Conventional	72	64	60	50	44	40	37	34	28	20

Fig 4. Graph shows the Kaplan-Meier survival analysis for assisted primary patency rates in patients with arterial anastomotic stenosis in the cutting and conventional percutaneous transluminal angioplasty (*PTA*) groups. No significant differences in assisted primary patency rates were identified between groups ($P = .921$). Note that the line is interrupted beyond the point at which standard error exceeds 10%. The number of patients at risk in each time period is listed.

Similarly, for the arterial anastomotic stenosis subgroup, the assisted primary patency for the cutting balloon angioplasty group (70% and 30% at 6 months and 1 year, respectively) vs the conventional balloon angioplasty group (62% and 49%) revealed no statistically significant differences ($P = .921$) (Fig 4).

Complications in cutting balloon angioplasty group. Rupture of the balloon during inflation occurred in three patients with no evidence of extravasation on angiography. Angiography performed 12 weeks after angioplasty showed aneurysmal dilation at the site of the treated lesion in one of these patients. The aneurysm was <2 cm in diameter, and no further diameter increase could be detected at 1-year follow-up after angioplasty, with no effect on hemodialysis. No other angioplasty-related complications were recorded in the cutting balloon angioplasty group.

Complications in conventional balloon angioplasty group. Rupture of the balloon during inflation occurred in two patients, with extravasation in one successfully managed by inflation of the balloon at lower pressure combined with external manual compression for 3 minutes. No other angioplasty-related complications were recorded in the conventional balloon angioplasty group.

DISCUSSION

There are widespread shortcomings in the published reports describing the use of cutting balloon angioplasty to treat hemodialysis vascular access stenosis.[7-12] First, these studies include the concurrent use of cutting and conventional balloon angioplasty, the use of a high pressure balloon, or a combination with placement of a stent after cutting balloon angioplasty. In other published studies, cutting PTA was used only after failure of high-pressure balloon angioplasty. In these reports, the long-term patency rate is not necessarily reflective of the results obtainable with cutting balloon angioplasty as a primary, stand-alone treatment. The cutting balloon was designed to reduce vascular trauma and thereby reduce neointimal hyperplasia to improve hemodialysis access long-term patency. One could theorize that concurrent use of a high-pressure angioplasty balloon might negate these conceptual benefits. Several studies have compared cutting balloon and conventional balloon angioplasty in treatment of vascular access stenoses with conflicting results.[13-21]

In our study, we found that the assisted primary patency was statistically higher in favor of cutting balloon angioplasty in contrast to conventional balloon angioplasty in dealing with stenosis of the graft-to-vein anastomosis. The small number of patients in the subgroups is a limitation of our study, and larger future studies are warranted. The assisted primary patency was not significantly improved by use of cutting balloon angioplasty for intragraft stenosis. Similar results were reported by Kariya et al[17] comparing cutting and conventional balloon angioplasty in the treatment of in-stent restenosis and intragraft stenosis, with cutting balloon angioplasty failing to achieve significant improvement in assisted primary patency. Such failure could be attributed to the resistance of the prosthetic graft material, which might resist cutting by the balloon microsurgical blades.

Balloon rupture occurred in three of our patients during cutting balloon inflation, with aneurysm formation at the angioplasty site in one of these patients detected 12 weeks after angioplasty. Aneurysm formation could be secondary to injury of the vessel wall by the cutting balloon microsurgical blades, so patients need to be observed for such a complication after cutting balloon angioplasty.

CONCLUSIONS

Cutting balloon angioplasty proved to be safe and effective in the treatment of graft-to-vein anastomotic stenosis, with significantly higher assisted primary patency than that of conventional balloon angioplasty.

AUTHOR CONTRIBUTIONS

Conception and design: HS, AK, MT, HA
Analysis and interpretation: HS, AK, MT, HA
Data collection: HS, AK, MT, HA
Writing the article: HS, AK, MT, HA
Critical revision of the article: HS, AK
Final approval of the article: HS, AK, MT, HA
Statistical analysis: HS, AK
Obtained funding: Not applicable
Overall responsibility: HS

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APPENDIX

Technique of percutaneous transluminal angioplasty (PTA).

Technique of cutting PTA. In cutting PTA, a 1- to 2-cm-long cutting balloon (peripheral and coronary cutting balloon; Boston Scientific, Natick, Mass) rated as having a burst pressure of 10 atm and with inflation diameter of 2.5 to 8 mm was used. The lesion was crossed with a 0.014-inch guidewire (Transend; Boston Scientific), over which the cutting balloon was introduced. First, the cutting balloon was inflated for 1 minute at 4 atm. On the second inflation, if the balloon waist remained at the same pressure as on the first inflation, pressure was subsequently increased by 2 atm and the balloon was inflated repeatedly until the balloon waist disappeared. Once the balloon was completely inflated for 1 minute on any attempt, the inflation procedure was terminated. Maximum pressure was set at 10 atm; even if the balloon waist remained after inflation at 10 atm, the inflation procedure was terminated. After an inflation end, the deflated cutting balloon catheter was rolled before the next inflation. The reason for rolling the cutting balloon catheter was so that the blade attached to the balloon would cut the stenotic lesion at a different site each time. At the end of the procedure, a final fistulogram was obtained.

Technique of conventional PTA. In conventional PTA, 2- to 4-cm-long conventional balloons (Coyote and Synergy; Boston Scientific) rated as having a burst pressure of 18 atm and with an inflation diameter of 2.5 to 8 mm were used. The lesion was crossed with a 0.035-inch guidewire (Terumo Medical Corp, Somerset, NJ), over which the balloon was introduced. Each balloon was inflated to a level below the rated burst pressure recommended by the manufacturer until the balloon waist disappeared; it was then inflated for 60 seconds. Even if the balloon waist remained after inflation at rated burst pressure, the inflation procedure was terminated without further attempt. At the end of the procedure, a final fistulogram was obtained.